4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 202

[Docket No. FDA-2009-N-0582]

RIN 0910-AG27

Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period on specific data.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on specific data related to a proposed rule published in the Federal Register of March 29, ,to establish standards that would be considered in determining whether the major statement in direct-to-consumer (DTC) television and radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans is presented in a clear, conspicuous, and neutral manner. In the Federal Register of January 27, 2012, FDA announced that it had added a document to the docket for the proposed rulemaking concerning a study entitled "Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements" (Distraction Study) and the public was given until February 27, 2012, to comment on this study as it relates to the proposed standards. FDA is reopening the

comment period for the rulemaking proceeding in response to a request for more time to submit comments to the Agency.

DATES: Submit either electronic or written comments on the Distraction Study report as it relates to the proposed standards by [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-N-0582 and/or Regulatory Information Number (RIN) 0910-AG27, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (For paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, docket number, and RIN for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products:

Ernest S. Voyard,

Center for Drug Evaluation and Research,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 51, rm. 3276,

Silver Spring, MD 20993-0002,

301-796-3832.

For information concerning human biological drug products:

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM–17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852–1448,

301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of March 29, 2010 (75 FR 15376), FDA published a proposed rule entitled "Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner," to amend its regulations concerning DTC advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), added by section 901(d)(3)(A) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (FDAAA). This section requires that the major statement in DTC television or radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans be presented in a clear, conspicuous, and neutral manner, and directs FDA to publish regulations establishing the standards for determining whether a major statement meets these requirements. As directed by section 901(d)(3)(B) of FDAAA, the proposed rule described standards that the Agency would consider in determining whether the major statement is clear, conspicuous, and neutral, and it provided a 90-day period for public comment, which closed on June 28, 2010.

On January 27, 2012 (77 FR 4273), FDA reopened the comment period on this rulemaking until February 27, 2012, to allow an opportunity for interested parties to comment on FDA's analyses of the results of its study (see attachment in Docket No. FDA-2009-N-0582-0040) on the impact of distraction on consumer understanding of risk and benefit information in DTC prescription drug television advertisements (72 FR 47051, August 22, 2007) (Distraction Study) as it relates to the proposed standards. The Pharmaceutical Research and Manufacturers of America (PhRMA) submitted a letter dated February 20, 2012, requesting an additional

15 days for interested persons to comment. FDA believes that an additional 15 days to comment on the Distraction Study as it relates to the proposed standards is appropriate.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the Distraction Study as it relates to the proposed standards. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document and label them "ATTN: Distraction Study." The data and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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